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10/587,864	07/28/2006	Didier Colavizza	Q95819	9777
23373 7590 12/22/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER BADR, HAMID R				
ART UNIT		PAPER NUMBER		
1781				
NOTIFICATION DATE		DELIVERY MODE		
12/22/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/587,864

Applicant(s)

COLAVIZZA ET AL.

Examiner

HAMID R. BADR

Art Unit

1781

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on RCE, 11/4/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/04/2010 has been entered.

1. Claims 17-42 are being considered on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Regarding claim 27, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 17-19 are rejected under 35 U.S.C. 102(a) over applicant's admissions at page 2 of the specification.
5. The rejection is maintained for the reasons of record. The applicants admit that the strains were deposited in 2003, and there is no means for the Patent Office to know which inventor or inventors contributed to which strains, or if they all did.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 17-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satoshi et al. (1994, Construction from a single parent of Baker's yeast strains with high freeze tolerance and fermentative activity in both lean and sweet doughs; hereinafter R1) in view of Hill (US 4, 318,991; hereinafter R2).

8. R1 investigates the hybridization process for generating hybrid *Saccharmyces cerevisiae* strains highly resistant to high sugar content in bread doughs. The hybrid baker's yeast strains as developed through hybridization can efficiently ferment doughs containing 30% sugar (Abstract, Materials and Methods, Table 1). R1 discloses the preparation of doughs using the developed strains. (Ingredients of doughs, Table 1 and dough raising test. Page 3500, col. 1). Given that R1 discloses yeast strains which can efficiently ferment doughs containing 30% sugar, it is obvious that these strains meet the requirement of claim 27 reciting the dough containing 15% sugar.

9. R1 is silent regarding the tolerance of the developed strains to preservatives (mold inhibitors) such as propionates and sorbates and also the preparation of various forms of baker's yeast.

10. R2 discloses a method in which baker's yeast is propagated in the presence of carboxylic acids having 2-4 carbon atoms such as propionic acid. Such baker's yeast is claimed to tolerate the antifungal carboxylic acids (e.g. propionic) during dough fermentation. (Col. 4, lines 13-33). Given that R2 discloses the propagation of baker's yeast in the presence of carboxylic acids having 2-4 carbon atoms, the requirements of claims 23 and 42 are met.

11. R2 also discloses a process for the preparation of compressed yeast and dry baker's yeast. (Col. 3, Lines 55-68). Therefore, claim 24, requiring the preparation of yeast creams, compressed yeast, and dry yeast, would be obvious.

12. It is also noted that calcium propionate has been known and used as antifungal compound in the baking art for a long time. Therefore, claim 28 which requires the presence of mold inhibitors would be obvious.

13. Despite the fact that applicants have provided specific deposit names (I-2971, I-3142, I-3143) for the isolated strains disclosed and claimed, this does not provide a patentable distinction over those strains disclosed by R1 as also possessing high sugar and freeze tolerance, absent any clear and convincing evidence and/or arguments to the contrary. The USPTO does not possess the facilities to test each strain of microorganism. However, a reasonable rejection has been set forth and thus the burden shifts to applicant to demonstrate that the strain of the reference is not, in fact, the same as that of the claimed strain. Alternatively, given the specific teachings of R1; one would have been motivated to produce high sugar and freeze tolerant strains

through utilization of standard techniques such as hybridization and mutation as known in the art, expecting to screen out strains having high sugar and freeze tolerance.

14. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to develop hybrids of baker's yeast to tolerate high sugar concentration in bread dough as disclosed by R1 and propagate such strains in the presence of carboxylic acids having 2-4 carbon atoms such as propionic acid as taught by R2. One would do so to acquire both high sugar tolerance and preservative tolerance in baker's yeast. Absent any evidence to contrary and based on the combined teachings of the cited references there would have been a reasonable expectation of success in developing the claimed *Saccharmyces cerevisiae* strains.

15. **Claims 17-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ando et al. (US 6,521,272; hereinafter R3) in view of Hill (US 4, 318,991; hereinafter R2).**

16. R3 discloses yeast to be tolerant to ultra-high sugar range, as well as high sugar and freeze tolerance yeasts. (Abstract)

17. R3 discloses the highly osmotolerant yeasts capable of sufficiently fermenting dough at a very high sugar concentration, such as dough containing sucrose in an amount of 30-50% baker's percent. (col. 6, Table 2 and the paragraph below, and Example 6)

18. R3 discloses one of the sugar tolerant strains to be P-731 (FERM BP-7035). (col. 3, lines 44-45). Also disclosed is P-712 tolerant to sucrose above 30-40 baker's percent. (col. 3, lines 7-9)

19. R3 discloses the methods of obtaining such osmotolerant yeasts (col. 3, lines 20-45).
20. R3 discloses methods of producing dough and bread thereof. (col. 4, line 64 to col. 5 line 2, and Example 2)
21. R3 discloses the method of propagating their inventive yeast. (col. 5, Example 1)
22. R3 is silent regarding the adaptation of yeast culture in the presence of carboxylic acids having 2-4 carbon atoms.
23. R2 discloses a method in which baker's yeast is propagated in the presence of carboxylic acids having 2-4 carbon atoms such as propionic acid. Such baker's yeast is claimed to tolerate the antifungal carboxylic acids (e.g. propionic) during dough fermentation. (Col. 4, lines 13-33). Given that R2 discloses the propagation of baker's yeast in the presence of carboxylic acids having 2-4 carbon atoms, the requirements of claims 23 and 42 are met.
24. R2 also discloses a process for the preparation of compressed yeast and dry baker's yeast. (Col. 3, Lines 55-68). Therefore, claim 24, requiring the preparation of yeast creams, compressed yeast, and dry yeast, would be obvious.
25. It is also noted that calcium propionate has been known and used as antifungal compound in the baking art for a long time. Therefore, claim 28 which requires the presence of mold inhibitors would be obvious.
26. Despite the fact that applicants have provided specific deposit names (I-2971, I-3142, I-3143) for the isolated strains disclosed and claimed, this does not provide a patentable distinction over those strains disclosed by R3 as also possessing high sugar

and freeze tolerance, absent any clear and convincing evidence and/or arguments to the contrary. The USPTO does not possess the facilities to test each strain of microorganism. However, a reasonable rejection has been set forth and thus the burden shifts to applicant to demonstrate that the strain of the reference is not, in fact, the same as that of the claimed strain. Alternatively, given the specific teachings of R3; one would have been motivated to produce high sugar and freeze tolerant strains through utilization of standard techniques such as hybridization and mutation as known in the art, expecting to screen out strains having high sugar and freeze tolerance.

27. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to develop hybrids of baker's yeast to tolerate high sugar concentration in bread dough as disclosed by R3 and propagate such strains in the presence of carboxylic acids having 2-4 carbon atoms such as propionic acid as taught by R2. One would do so to acquire both high sugar tolerance and preservative (i.e. calcium propionate) tolerance in baker's yeast. Absent any evidence to contrary and based on the combined teachings of the cited references there would have been a reasonable expectation of success in developing the claimed *Saccharmyces cerevisiae* strains.

Response to Arguments

Applicants arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

1. Applicants argue that Satoshi (R1) uses TYR (yeast strain) as the only starting material which is a freeze tolerant strain and not a sugar tolerant strain while the present invention involves hybridizing diverse organisms which are totally unrelated.
 - a. This argument is irrelevant. The hybrid yeasts of Satoshi meet the requirement of claim 27. Satoshi's hybrids are tolerant to osmotic pressure in doughs containing 30% sugar. Therefore, they tolerate at least 15% sugar as presently claimed in claim 27.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process", *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) . Further, "although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product", *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). See MPEP 2113.
2. Applicants argue that mode of production by Satoshi is a laboratory scale.
 - a. This argument is irrelevant, because all yeasts should be prepared in a laboratory first. Even in industrial set ups, the seed yeast is first propagated in a test tube in a laboratory.

3. Applicants argue that a yeast strain which has a certain efficiency when produced in a laboratory batch process will generally not have the same efficiency in an industrial fed batch process.
 - a. This argument has no scientific basis. The issue at hand is a strain of baker's yeast which is sugar and freeze tolerant as disclosed by Satoshi. This disclosure makes the presently claimed strains obvious.
4. Applicants argue that strains produced at laboratory level will be useless.
 - a. All inventive microorganism including the presently claimed strains of baker's yeast are first propagated and prepared in laboratories. The scale up process is a multi-stage operation. Therefore the argument does not appear to be a sound argument.
5. Applicants have tried to make a comparison of the claimed strains with those disclosed by Satoshi. They compare the carbon dioxide generation, as means of efficiency, in claimed strains and those of Satoshi. They assert that in Satoshi experiments for 100 parts of flour there is 0.99 parts yeast dry matter and in the claimed invention, there is 2.88 part dry yeast per 100 part flour. They conclude that regarding carbon dioxide generation, the claimed strains are more efficient than Satoshi's strains.
 - a. In previous Office actions it was discussed and explained that experiments of the prior art and those as presently carried out cannot be compared because of various factors involved. The dough as disclosed by Satoshi is a different dough, the controls are different for Satoshi experiments and the proof time, as presently claimed, cannot be simply compared to the volume of carbon dioxide evolve as disclosed by Satoshi.

Satoshi reports the volume of carbon dioxide in a dough comprising only 4 components. The amount of carbon dioxide evolved in these experiments is being compared to decrease in proof time, as presently claimed, of a dough comprising many other ingredients. The dough fermentation and the resulting carbon dioxide generation is a function of dough ingredients. One cannot compare two different systems together and conclude that the claimed invention is more efficient.

b. Applicants are projecting proof time to have a linear relationship with carbon dioxide volume generated. Then they conclude that if only 990 mg yeast dry matter is used instead of 2880 mg yeast dry weight, as in the instant experiments, the presently claimed strains are still more efficient in a dough containing 40% sugar. However, it should be realized that carbon dioxide is not produced by yeast dry matter. The yeast gets activated in the dough, and then logarithmically grows producing a lot more cells and the dough fermentation and the resulting carbon dioxide formation is a function of yeast cell growth. Therefore, one can not assume that when they start with 990 mg yeast dry matter instead of 2880 mg yeast dry matter, as presently asserted, the carbon dioxide production of two different situations can be compared.

Given the conditions, it is fair to say that the presently claimed strains are not patentable over those of Satoshi.

6. Applicants argue that R2 teaches how to propagate yeast in the presence of organic acids but does not disclose any method of producing new sugar tolerant yeast strain.

a. The production of strains which are both sugar and freeze tolerant is disclosed by R1. R2 is a secondary reference which does not have to disclose all of the features of the presently claimed invention.

However, note that while R2 does not disclose all the features of the present claimed invention, R2 is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr
Examiner
Art Unit 1781

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781